29. (Original) The method of claim 27, said probability decreasing as said measured optical density decreases.

30. (Original) The method of claim 27, further comprising the step of using said measured optical density to determine whether said sample contains chronic HCV infection.

Remarks:

Claims 1-30 remain for consideration in this application with claims 1, 12, 19, and 26 being in independent format. Applicant respectfully asserts that in view of the amendments and remarks herein, the rejections of the Office Action dated December 3, 2003 are traversed or should be withdrawn.

Claims 1-30 were rejected under 35 U.S.C. 112, second paragraph for indefiniteness. Specifically, it was allegedly unclear in claim 1 whether the phrase "determining an optical density" was a part of, or was in addition to "performing an HCV antibody-based assay." In response, applicant asserts that claim 1 is not unclear. Claim 1 is for a method of identifying individuals having a certain probability of having chronic HCV infection. The method comprises these four steps: 1) obtaining a fluid sample from the individual; 2) performing an HCV antibody-based assay on said sample; 3) determining the optical density of said sample; and 4) using said determined optical density to identify individuals having said certain probability of having chronic HCV infection. As explained in the specification at page 2, lines 13-22, it is impossible to determine whether an individual testing positive for HCV in an antibody-based assay has chronic HCV infection or if they have cleared the infection and merely have residual antibodies against HCV. One way to confirm that individuals testing positive in an antibody

based assay have chronic HCV infection is to perform an HCV RNA test, which is very expensive. As described on page 3, line 11 to page 4, line 5, the present invention allows a prediction to be made about whether an individual testing positive for HCV infection has chronic HCV or has cleared the infection by performing the recited steps. Each of the recited steps is a separate step that is in addition to the other recited steps. Accordingly, applicant respectfully requests the withdrawal of this rejection.

Claim 2 was allegedly unclear due to the recitation of "said optical density determining step occurring only on said samples testing positive in said HCV antibody-based assay." This claim merely describes a preferred embodiment of the invention wherein only samples that test positive for HCV antibodies in an antibody-based assay are subsequently analyzed for their optical density. Such a step serves to further reduce the number of tests that a lab would have to run on a set of samples. Accordingly, applicant respectfully requests the withdrawal of this rejection.

Claim 3 was allegedly unclear due to the recitation of "said performing step including the step of contacting said sample with a quantity of HCV antibodies." This claim has been amended to recite that the sample is contacted with a quantity of HCV antigen and not antibodies as was previously recited. Accordingly, applicant asserts that this rejection has been traversed.

Claim 12 was allegedly indefinite because it disclosed only a single process step. Applicant asserts that claim 12, which claims a method of predicting whether an individual providing a fluid sample testing positive for HCV antibodies has chronic HCV infection, actually has two steps therein. The first step is measuring the optical density of said fluid sample. This "said fluid sample" is a fluid sample from the HCV antibody assay test step from this Jepson-style claim. That is to say that the fluid sample has already been a part of an HCV

antibody assay. This is followed by the second step wherein the measured optical density is correlated with the probability that the individual providing the fluid sample has chronic HCV infection. Accordingly, applicant respectfully requests that this rejection be withdrawn.

Claims 15-18 and 22-25 were allegedly indefinite because "An optical density value standing alone is meaningless." Applicant asserts that this is a true statement unless the readings are taken in the context of being read along with positive and negative controls and following the instructions available in any commercially available kit, as would be done by one of ordinary skill in the art and as was done for this application. Accordingly, applicant respectfully requests that this rejection be withdrawn.

Claim 19 was rejected for alleged indefiniteness of the step "contacting said fluid sample with HCV antibodies." This phrase has been deleted from the claim and therefore, applicant asserts that this rejection has been traversed.

Claim 26 was allegedly indefinite because it was unclear which process "measuring the optical density" or "performing an antibody based assay" was being claimed. Additionally, claim 26 was alleged to indefinite because the preamble was never correlated with any final results. Applicant notes that this claim has been amended to include the limitation "using said measured optical density to test for chronic HCV infection." Such a step correlates the final results, the measured optical density, to test for chronic HCV infection. Accordingly, applicant asserts that this rejection has been traversed.

Claims 1,4-11, 12-14, and 26-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/26673 to Scheffel et al. (Scheffel). Each of these rejected claims requires the step of determining the optical density of the sample. Additionally, the present claims have been amended to include the limitation that the antibody assay is capable of

detecting more than one HCV antibody. Such an assay is neither taught nor suggested by Scheffel and is in fact taught away from. In rejecting claims under 35 U.S.C. §103, the Patent Office bears the initial burden of presenting a *prima facie* case of obviousness. A *prima facie* case of obviousness is established against claimed subject matter when the teachings from the prior art itself would appear to have suggested that claimed subject matter to a person of ordinary skill in the art. If the Patent Office fails to establish a *prima facie* case, the rejection is improper and will be overturned. *In re Rijckaert,* 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). MPEP §706.02(j) addresses rejections under 35 U.S.C. §103 over prior art. This rule sets out three criteria that must be met in order to establish a *prima facie* case of obviousness: (1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine their teachings. (2) There must be a reasonable expectation of success. (3) The prior art reference (or combination of references) must teach or suggest all the claim limitations. MPEP §706.02(j), *citing In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The Rule further notes the initial burden is on the Examiner to provide some suggestion of desirability of doing what the inventor has done. Only if that burden is met does the burden of coming forward with evidence or argument shift to the applicant.

In the present application, none of the three requirements has been met. With respect to the first requirement for establishing a *prima facie* case, that there be some suggestion or motivation to modify the cited reference, the reference strongly teaches away from using an assay that is capable of detecting more than one HCV antibody. This is because Scheffel teaches that anti-E2 is the only antibody correlated with chronic HCV infection. Accordingly, all of the teachings of Scheffel relate to the detection of anti-E2 and exclude any suggestion or motivation

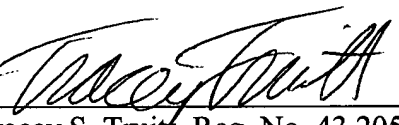
to assay for other antibodies. Scheffel discloses that "these methods are based upon the discovery that chimpanzees and humans having chronic infection show a higher frequency of development of antibodies to E2 and higher E2 antibody titer than those having self limited infection" (page 10, lines 18-22). Moreover, it is taught that anti-E2 antibodies do not play a role in the mechanism of self-limitation of HCV infections and that they develop earlier, more frequently, and to a higher titer in chimpanzees and in humans developing chronic infection (page 10, line 30 - page 11, line 4). The second requirement of establishing that there is a reasonable expectation that the modification of the cited reference would succeed is also not met in the present application. Again, the strong teaching away of using an assay that detects more than one HCV antibody necessitates such a finding. "The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art . . . Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." *In re Dow Chemical Co.*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988); *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442, 1444 (Fed. Cir. 1991). As discussed above, the Scheffel reference did not suggest the desirability of an HCV test which used an assay testing for the presence of more than one HCV antibody and certainly did not suggest that such a test would have any reasonable likelihood of success. References that fail to suggest likely success or achievement of a claimed result may be tantamount to "skepticism of an expert" and are probative of nonobviousness. *In re Dow Chemical Co.*, 5 U.S.P.Q.2d at 1532. Furthermore, it is improper to assess the potential success of the present invention under an "obvious to try" or "obvious to experiment" standard. *Id.* at 1532. Thus, the rejection does not support a prima facie case of obviousness because the cited reference does not suggest the

proposed modification to the method and because there can be no reasonable expectation that the proposed modification to the method would be successful. Applicant respectfully asserts that this rejection has been traversed.

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited.

Respectfully submitted,

By 

Tracey S. Truitt, Reg. No. 43,205
2405 Grand Boulevard, Suite 400
Kansas City, Missouri 64108
816/474-9050

ATTORNEYS FOR APPLICANT